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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,556	08/25/2000	Bernward Scholkens	02481.1702	3278

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EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/645,556	SCHOLKENS ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Pap r No(s) *7,8,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the first office action of June 20, 2001, submitted December 20, 2001 (Paper No. 10) is acknowledged.

Applicant's remarks and amendment is persuasive to remove the rejections under 35 USC 102 and 112 in the previous office action.

Claims 4-18 are herein examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Maclaughlan et al. (WO 96/24373).

Maclaughlan et al. (WO 96/24373) discloses pharmaceutical compositions comprising ACE inhibitors generally and alacepril, benazepril, captopril, cilazapril, delapril, enalapril, enalaprilat, fosinopril, fosinoprilat, imidapril, lisinopril, prindopril, quinapril, ramipril, temocapril, trandolapril, ceranapril, moexipril, quinaprilat, spriapril, see particularly claims 1-5. The ACE inhibitor may be present in an amount from 1 to 200 mg, see page 31, lines 27-35 in particular.

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by FDA Orange Book Active Ingredient Detail Record Search.

FDA Orange Book Active Ingredient Detail Record Search discloses a pharmaceutical composition comprising candesartan cilexetil as the active ingredient.

Note that the recitation of intended use does not further limit a claim drawn to a composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 and 10-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maclaughlan et al. (WO 96/24373).

Maclaughlan et al. (WO 96/24373) discloses the employment of ACE inhibitors generally and alacepril, benazepril, captopril, cilazapril, delapril, enalapril, enalaprilat, fosinopril, fosinoprilat, imidapril, lisinopril, prindopril, quinapril, ramipril, temocapril, trandolapril, ceranapril, moexipril, quinaprilat, spriapril specifically in a co-therapy in patients susceptible to congestive heart failure, see particularly claims 1-5, 9 and 11, see also page 7, lines 1-25. The ACE inhibitor may be present in an amount from 1 to 200 mg, see page 31, lines 27-35 in particular.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an ACE inhibitor in a method of preventing congestive heart failure in a patient.

One of ordinary skill in the art would have been motivated to employ an ACE inhibitor in a method of preventing congestive heart failure in a patient because ACE inhibitors are known to be employed of methods of preventing circulatory disorders such as congestive heart failure in patients, see for example lines 1-25, page 7 of Maclaughlan et al.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (USPN 5,196,444).

Naka et al. (USPN 5,196,444) teaches the employment of a pharmaceutical composition comprising candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the treatment of heart diseases and hypertension, see abstract and claims 1-9 in particular.

Naka et al. does not particularly teach the employment of its composition in the prevention of CHF.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the treatment of CHF.

One of ordinary skill in the art would have been motivated to employ candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the prevention of CHF because development of CHF typically arises from essential hypertension or from heart conditions following myocardial infarction. Therefore an active agent that is known to treat hypertension and heart diseases generally, would be reasonably expected to prevent CHF.

Response to Arguments

Applicant's arguments filed 12/20/01 concerning Maclaughlan have been fully considered but they are not persuasive. Applicant argues that the population of MacLaughlan does not have

an essentially maintained heart function. Note that MacLaughlan generally teaches the employment of an ACE inhibitor for the treatment or prevention of circulatory disorders including CHF, see for example page 7, lines 5-25.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
July 22, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200